REMARKS

A. Status of the Claims

Claims 36-56 were pending at the time of the Office Action with claims 53-56 being withdrawn as directed to a non-elected invention. Applicants note that while page 2 of the Action identifies claims 53-56 as withdrawn, the Office Action Summary incorrectly indicates that claims 36-52 are withdrawn. Claims 36-41 and 43 have been amended. Support for the amendments can be found throughout the specification including, for example, at page 4. Claims 42, 44, 46 and 52 have been canceled. Thus, claims 36-41, 43, 45 and 47-56 are now pending.

B. Objection to the Specification

The Action objected to the specification because it contains an embedded hyperlink on pages 4, 49 and 57. The specification has been amended to remove the referenced embedded hyperlinks on pages 4 and 49, and an additional embedded hyperlink on page 37. Applicants were unable to identify the embedded hyperlink on page 57 referred to in the Action. Applicants therefore request withdrawal of the objection.

C. Double Patenting

Double patenting under 35 U.S.C. § 101 is mentioned on page 3 of the Action, but no pending claims are mentioned as being rejected nor are any claims of another patent identified upon which such a rejection could be based. This section of the Action proceeds to state that should claim 36 be found allowable, claims 42-44 and 51-52 stand objected to under 37 C.F.R. § 1.75 as being a substantial duplicate thereof. This, however, does not provide a basis for a double patenting rejection under 35 U.S.C. § 101. In view of the above, the reference to double patenting under 35 U.S.C. § 101 appears to have been made in error.

With regard to the objection to claims 42-44 and 51-52 under 37 C.F.R. § 1.75 as being a substantial duplicates of claim 36, Applicants note that claims 42, 44 and 52 have been canceled rendering this objection moot as to those claims. Claim 43 further limits the isolated hyperimmune serum-reactive antigen or fragment of claim 36 by specifying that the antigen is in a pharmaceutical composition. Claim 51 further limits claim 43 by specifying that the pharmaceutical composition of claim 43 is a vaccine. As such, claims 43 and 51 are not substantial duplicates of claim 36. An objection under 37 C.F.R. § 1.75 is, therefore, improper.

D. Rejection Under 35 U.S.C. § 101

The Action rejects claims 36-52 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. In particular, the Action states that the claims are directed to a product of nature. Applicants have amended the claims such that they specify that that the hyperimmune serum-reactive antigen is "isolated." Support for this amendment may be found in the specification at, for example, page 4. Applicants therefore respectfully request withdrawal of the rejection.

E. Claim Objections under 37 C.F.R. § 1.75(c)

Claims 42, 44-46 and 51-52 stand objected to under 37 C.F.R. § 1.75(c) for failing to further limit the subject matter of a previous claim. Claims 42, 44, 46 and 52 have been canceled. Claim 45 further limits the subject matter of claim 43 by reciting that the pharmaceutical composition comprises "at least two different hyperimmune serum-reactive antigens and/or fragments." Claim 51 further limits the pharmaceutical composition of claim 43 by specifying that the pharmaceutical composition is a vaccine. Not all pharmaceutical compositions are vaccines; thus, reciting that the pharmaceutical composition is a vaccine further limits the subject matter of claim 43. As such, claims 45 and 51 further limit the subject matter of claim 43. Withdrawal of the objection is therefore respectfully requested.

F. The Claims Are Enabled

The Action rejects claims 43-52 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Action acknowledges that the specification is enabling for a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising the amino acid sequence SEQ ID NO:91. The Action asserts, however, that the specification does not reasonably provide enablement for a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising any fragment of SEQ ID NO:91. Applicants traverse this rejection.

The specification provides the complete structure of SEQ ID NO:91, and the Action concedes that the specification provides guidance on how to make a hyperimmune serum-reactive antigen comprising SEQ ID NO:91. Based on the disclosure of SEQ ID NO:91, a person of ordinary skill in the art can readily identify and make a hyperimmune serum-reactive antigen comprising a fragment of SEQ ID NO:91. Contrary to the Action's assertion that the

specification fails to teach the amino acid sequence of at least one hyperimmune serum reactive antigen comprising a fragment of SEQ ID NO:91 (Action, p. 6), the specification demonstrates that a fragment of amino acids 2-14 of SEQ ID NO:91 was highly reactive with individual human sera (Example 4 and Table 2). Further, Example 5 and Table 1 disclose predicted immunogenic fragments of amino acids 4-10 and 16-28 of SEQ ID NO:91 and predicted class I and class II T cell epitopes amino acids 3-14 and 16-30 of SEQ ID NO:91. The specification also provides general guidance in regard to predicted immunogenic amino acids, predicted class II-restricted T cell epitopes, predicted class I-T cell epitopes, and the identification of immunogenic regions (*e.g.*, specification at page 63).

Furthermore, assessing whether an isolated hyperimmune serum-reactive antigen comprising an immunogenic fragment of SEQ ID NO:91 was capable of eliciting an immune response would not require undue experimentation because it could be accomplished by routine screening using methods such as those described in Example 4 in the present specification (*see In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). For example, Example 4 shows the immunogenicity of fragments wherein the function has been tested with an antibody titer collected from patient with *C. pneumoniae* infection.

Further, the term "hyperimmune serum-reactive" as used in the application refers to the fact that the identified antigens were screened with antibody preparations of individuals with an immunity or reactive immune system to *C. pneumoniae* (*see e.g.*., p. 13, para. 5 to p. 14, para. 3). By using individual sera from individuals previously infected by *C. pneumoniae*, antigens with proven capable of stimulating immunity are identified. Thus, the hyperimmune serum-reactive antigens are necessarily capable of eliciting an immune response, because they were identified by antibodies already present in patients infected by *C. pneumoniae*.

In view of the above, the present specification contains a description sufficient to enable one skilled in the art to make and use the claimed invention without unduly extensive experimentation. Applicants, therefore, respectfully request the withdrawal of the rejection.

G. Indefiniteness Rejection

The Action rejects claims 42, 44 and 46 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Action asserts that the term "directed against" is vague. This rejection is moot in view of the cancellation of claims 42, 44 and 46.

H. The Rejections Under 35 U.S.C. § 102(b) Are Overcome

1. The Read Reference

The Action rejects claims 36-42 under 35 U.S.C. § 102(b) as being anticipated by Read *et al.* (*Nucleic Acids Research*, Vol. 28, p. 1397-1406, 2000) as evidenced by *C. pneumonia* AR39 genome accession numbers AE002161 and AAF38131. Specifically, it is asserted that Read teach a genomic sequence of *C. pneumoniae* comprising the amino acid sequence of SEQ ID NO:91 and further that the protein of Read will inherently be hyperimmune serum reactive.

Claims 36-41 currently recite an isolated hyperimmune serum-reactive antigen consisting of a specified amino acid sequence. The cited reference sequences comprise amino acids not encompassed by the currently claimed sequences, and there is no teaching or suggestion to make the specific sequences encompassed by the current claims. Further, the antigenicity of the claimed protein sequences was not taught or suggested in Read or the cited genomic sequences. Given the closed construction of the amino acid sequences in the claims and a lack of teaching or suggestion regarding the antigenicity of the claimed sequences, the reference does not anticipate the claimed invention. Withdrawal of the rejection is therefore respectfully requested.

2. The Murdin Reference

The Action also rejects claims 43-48 and 51-52 under 35 U.S.C. § 102(b) as being anticipated by Murdin *et al.* (*The Journal of Infectious Diseases*, 2000; 181 (Suppl. 3):S544-51) as evidenced by accession numbers AE002161 and AAF38131. In particular, it is asserted that Murdin teach a pharmaceutical composition comprising heat killed *C. pneumoniae* AR39 diluted in SPG buffer that comprises a hyperimmune serum-reactive antigen comprising an amino acid sequence of SEQ ID NO:91 and therefore anticipate the claimed invention. Applicants respectfully traverse.

Murdin does not anticipate the current claims because Murdin does not teach a pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen consisting of an amino acid sequence of SEQ ID NO:91. The claims of the current invention relate to a pharmaceutical composition comprising an ***isolated*** hyperimmune serum-reactive antigen. In contrast, Murdin describes a whole cell *Chlamydia pneumonia* AR39 preparation and does not teach or suggest the isolation of the currently claimed sequences. Further, none of the cited references teach or suggest the antigenicity of the Cp_0271 putative protein of the genomic data base, and therefore the references do not teach or suggest a pharmaceutical composition containing such an isolated antigen. Accordingly, Murdin does not teach or suggest the pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen of the current invention.

In view of the above, claims 43-48 and 51-52 are novel over Murdin. Applicant, therefore, requests the withdrawal of the rejection.

I. The Rejections Under 35 U.S.C. § 103(a) Are Overcome

1. The Read and Meinke References

The Action rejects claims 43-44 and 47-52 under 35 U.S.C. § 103(a) as being unpatentable over Read, as evidenced by accession numbers AE002161 and AAF38131, in view of Meinke *et al.*(WO 02/059148). In particular, the Action alleges that one of ordinary skill in the art would have been motivated to make a pharmaceutical preparation of the composition of Read as taught by Meinke. Applicants respectfully traverse.

As noted above, the cited reference sequences comprise amino acids not encompassed by the currently claimed sequences, and there is no teaching or suggestion to make the specific sequences encompassed by the current claims. Further, as outlined above, the antigenicity of the claimed sequences was not shown in Read and Meinke. In fact, the CP_0271 protein noted in the Action is only indicated as a putative protein without further information to provide the skilled man in the art any guidance for pharmaceutical uses. As neither reference suggests to include an antigen consisting of SEQ ID NO:91 or a fragment thereof in a pharmaceutical composition, the rejection appears to be based purely on impermissible hindsight. Withdrawal this rejection is therefore respectfully requested.

2. The Murdin and Meinke References

The Action also rejects claims 43-52 under 35 U.S.C. § 103(a) as being unpatentable over Murdin, as evidenced by accession numbers AE002161 and AAF38131, in view of Meinke *et al.* (WO 02/059148). Specifically, the Action alleges that one of ordinary skill in the art would have been motivated to use other immunostimulatory substances in the pharmaceutical preparation of Murdin as taught by Meinke. Applicants respectfully traverse.

As noted above, Murdin describes a whole cell *C. pneumonia* AR39 preparation and does not teach or suggest the the currently claimed isolated hyperimmune serum-reactive antigen. Additionally, Meinke does not provide any further guidance regarding the currently claimed protein sequences. As such, the cited references do not teach or suggest the antigen of the genomic sequences for which no antigenicity could be assumed. With no guidance regarding the antigenicity of the genomic sequence, one of skill in the art would not have had a reason to isolate an amino acid sequence consisting of SEQ ID NO:91 or a fragment thereof and include the claimed isolated antigen in a pharmaceutical composition. Thus, the cited references do not render obvious all of the elements of the claims. Accordingly, the Action does not establish a *prima facie* case of obviousness and the rejection should be withdrawn.

J. Conclusion

In view of the foregoing, Applicants submit that the claims are in condition for allowance and an early indication to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-5654 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

Travis M. Wohlers
Reg. No. 57,423
Attorney for Applicant

FULBRIGHT & JAWORSKI L.L.P.
(Customer No. 32425)
600 Congress Avenue, Suite 2400
Austin, Texas 78701
512.536.5654 (voice)
512.536.4598 (fax)

Date: September 4, 2007